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SUBJECT: CHILE UNABLE TO EXPLAIN IPR REGIME TO USTR

REF: A. SANTIAGO 1562

[1](#)B. SANTIAGO 1230
[1](#)C. SANTIAGO 380

[1](#)1. (SBU) Summary. Assistant USTR Eissenstat visited Santiago August 10-11 as part of Chile's Out of Cycle Review under the Special 301 Process. Eissenstat met with a panel from the Ministries of Health and Foreign Affairs and patent office. The GOC was unable to explain how its system provides IPR protection for proprietary data and patents. It was adamant it had made the legal and bureaucratic changes to comply with the U.S.-Chile Free Trade Agreement. The GOC is worried IPR enforcement will be costly and ultimately restrict consumer access. USTR will continue OCR-related talks with the GOC over the coming months but left Santiago more concerned about Chile's IPR protection than before it arrived. End Summary.

[1](#)2. (SBU) Assistant U.S. Trade Representative Everett Eissenstat headed a delegation of USTR and Food and Drug Administration officials to Santiago August 10-11 as part of Chile's Out of Cycle Review (OCR) under the Special 301 Process. Chile is currently on the Watch List. The main goals of Eissenstat's visit were to understand how and if, two and a half years into the U.S.-Chile FTA, the GOC provides data and patent protection for pharmaceuticals.

[1](#)3. (SBU) GOC officials were defensive in the talks and clearly concerned about the outcome of the OCR. The GOC was eager for acknowledgement from Eissenstat that it has made progress in establishing an effective IPR regime. The GOC maintained a hard line that it was complying with the FTA, while privately admitting there had been blatant patent violations in recent years. The GOC maintained there would at least be fewer violations in the future but was unable to explain how it would accomplish even this.

Data Protection

[1](#)4. (SBU) The GOC held out Decree 153, published in December 2005, as a major step forward in providing data protection for innovative pharmaceuticals. It appears Decree 153 does offer some basic data protection and at least two innovative drugs have been granted data protection in the last six months under its provisions. The decree does require that the Instituto de Salud Publica (the ISP is the rough equivalent of the FDA) not disclose protected data and not rely on it for the approval of generics. That being said, there are many technical barriers, which are not allowed under the FTA, to receiving data protection.

No Linkage Exists

15. (SBU) Despite the FTA's language requiring both parties to deny approval to pharmaceuticals that infringe on existing patents, the GOC has not created any clear system to accomplish this. There is a fundamental disconnect inside the GOC between the approval actions of health officials at the ISP and the Patent Office (Industrial Property Office). At times with Eissenstat, the GOC played semantics by insisting the ISP grants only sanitary approval and thus does not grant the marketing approval listed in the FTA. When pressed to delineate the marketing approval process and how sanitary approval fits into the mix, GOC officials were outright unable to do so. The final GOC response was that the court system provided the linkage demanded by the FTA. Seeking redress for patent violations through Chile's courts is time consuming, usually fruitless and completely pointless if the copy has already hit the market.

Conclusion

16. (SBU) The GOC's inability to explain its system only elevated USTR's concern. While Chile may have made an effort to provide some IPR protection, it is simply hard to tell at this point what (if anything) it has created. The current level of IPR protection for pharmaceuticals in Chile is muddled at best and at worst simply an effort to keep the U.S. at bay. Data protection is dictated by technical barriers and is far from automatic. Patents are not protected by the GOC and if there are violations, the courts provide the only potential recourse. Essentially, the GOC has taken its own responsibility to protect data and patents as stipulated by the FTA and placed that burden on individual companies. USTR will continue an OCR-related dialogue with the GOC over the coming months but this visit raised more questions than it answered. At this point, a USG inter-agency decision based on the OCR is expected to be made in October.

Comment

17. (SBU) It is President Bachelet herself who likely will have to decide if Chile is going to comply with its FTA obligations. The GOC has been resisting enforcing IPR, because it is worried about the costs to its national health care system (Plan Auge) and to the average consumer. The GOC has reportedly commissioned a study, due for completion in October, of the financial impact of fully respecting IPR. It is hard to predict what conclusions that study will draw. However, it seems clear that should estimates come in on the high side, the GOC will likely continue to try to create the illusion of IPR protection while doing little to fulfill its FTA promises.

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